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FDA: Omontys injection pulled from market

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Affymax Inc. of Palo Alto, Calif., and Takeda Pharmaceuticals Company Limited of Deerfield, Ill., have voluntarily recalled all lots of Omontys Injection, used to treat anemia in adult dialysis patients, following reports of serious and fatal hypersensitivity reactions, according to a safety recall issued by the U.S. Food and Drug Administration.

(HealthDay)—Affymax Inc. of Palo Alto, Calif., and Takeda Pharmaceuticals Company Limited of Deerfield, Ill., have voluntarily recalled all lots of Omontys Injection, used to treat anemia in adult dialysis patients, following reports of serious and fatal hypersensitivity reactions, according to a safety recall issued by the U.S. Food and Drug Administration.

The recall comes after reports of some patients experiencing serious and fatal hypersensitivity reactions following receipt of a first dose of Omontys, given by intravenous injection. The reactions, which occured within 30 minutes following the dose, were not reported following subsequent dosing or in patents who had completed their dialysis session.

The FDA has received 19 reports of anaphylaxis from dialysis centers

around the United States, three of which resulted in death. Other patients required rapid medical intervention or hospitalization. Reports included patients who were able to be resuscitated.

"Due to the severity of the public health risk, we want to be certain that health care providers stop using Omontys," Howard Sklamberg, J.D., director of the Office of Compliance at the FDA's Center for Drug Evaluation and Research, said in a statement. "Americans deserve medications that are safe, effective, and of the highest quality. We are investigating the products and facilities associated with this recall and will provide updates as we learn more."

More information: More Information